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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,919	08/26/2003	Paul Joseph Dominowski	15634 (PC25246)	2440

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,919	DOMINOWSKI, PAUL JOSEPH	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-23,25,27-77 and 79-82* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 32-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-5, 7-23, 25, 27-77 and 79-82 are pending. Claims 12-19 and 32-75 have been withdrawn from consideration. Claims 6, 24, 26, 78 and 83 have been canceled. Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 are under examination.

Comment [BC1]: You need to consider the rule 48 petition. See MPEP 201.03 for all the details. Requirements are different for each section of the rule. In this case, I see 2 problems. First, the statement re lack of deceptive intent needs to be made by the inventors being added, not by the atty. Second, they don't have anything showing consent of the assignee (there is an assignee - you know how to check this, right?). So go out with FP 2-13 telling them what the problems are.

Inventorship

The request to correct the inventorship of this nonprovisional application under 37 CFR 1.48(a) is deficient because:

The statement of facts by an inventor or inventors to be added or deleted does not explicitly state that the inventorship error occurred without deceptive intent on his or her part or cannot be construed to so state.

It lacks the written consent of any assignee of one of the originally named inventors.

Response to Arguments

The rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Talens et al. or Bowland et al. in view of Pruette et al. and Wilson et al. **is withdrawn**. Applicant's arguments, filed January 9, 2008, with respect to Attachments 1-3 have been fully considered and are persuasive.

The rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. in view of Brake et al. (US Patent No. 6,787,146, Sep. 2004) **is withdrawn** pursuant Applicant's arguments and Attachments 1-3.

New Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. and Fulton et al. (Vaccine, 15 September 2000, Vol. 19, No. 2-3, pages 264-274) in view of Brake et al. (US Patent No. 6,787,146, Sep. 2004, Publication 16 May 2002, US2002/0058046).

The claimed invention is drawn to an immunogenic and a vaccine composition comprising a modified live Bovine Herpesvirus Virus (BHV-1), a modified live Parainfluenza Virus Type 3 (PI-3), a modified live Bovine Respiratory Snycytial Virus (BRSV), an adjuvant, Bovine Viral Diarrhea Virus Type-1 (BVDV-1), a Bovine Viral Diarrhea Virus Type-2 (BVDV-2) and a veterinary-acceptable carrier, wherein BVDV-1 and BVDV-2 are inactivated, wherein said adjuvant comprises a saponin, a saponin-containing oil-in-water emulsion, Quil A, lecithin and oil blend, and cholesterol, wherein said adjuvant is microfluidized, wherein the immunogenic and vaccine composition further comprises a *Leptospira* or *Campylobacter fetus* antigen, wherein BVDV-1 and BVDV-2 is cytopathic or noncytopathic.

Bowland et al. discloses current commercial vaccines available in Canada for bovine respiratory disease. Vaccines include infectious bovine rhinotrachetitis virus [(IBRV), bovine

herpesvirus-1, (BHV-1)], bovine viral diarrhea virus (BVDV), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including *Leptospira* serovars (page 33 and Table 1 pages 43-45). Some of the multi-vaccines included adjuvants (Table 1, pages 43-45). Bowland teaches the vaccine compositions and intended use of the multi-vaccines.

Bowland et al. do not teach a vaccine composition comprising BVDV types 1 and 2. Bowland et al. do not teach a vaccine composition with an adjuvant comprising Quil A, Amphigen (lecithin and oil blend) and cholesterol.

Fulton et al. (hereinafter Fulton) teaches a vaccine composition comprising BVDV types 1 and 2 (see Table 1, Vaccine 3). Fulton also teaches BVDV has two biotypes, cytopathic (CP) and noncytopathic (NCP) (page 264, 1st column). Fulton further teaches vaccine containing modified live virus (MLV) (page 264, 2nd column).

Brake et al (hereinafter Brake) discloses a vaccine for cattle against bovine Neospora comprising a veterinary acceptable adjuvant comprising SEAM62 (column 8, lines 36-50). SEAM62 is an oil-in-water emulsion containing Quil A, lecithin and cholesterol (column 12, lines 59-67).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use BVDV types 1 and 2 for protection against BVDV 1 and 2. The person of ordinary skill in the art would have been motivated to use both BVDV types 1 and 2 because Fulton teaches both types cause disease in cattle, and reasonably would have expected success because of the teachings of Bowland and Fulton.

As set forth in *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980), It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same

purpose, in order to form a third composition which is to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in prior art. In this case, the common purpose is vaccination of cattle against viral diseases. Furthermore, combination vaccines were already known and used in the art, as discussed above.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use an oil-in-water emulsion adjuvant for the immunogenic or vaccine composition. The person of ordinary skill in the art would have been motivated to use an oil-in-water emulsion adjuvant because Brake teaches the preparation is a veterinary acceptable adjuvant, and reasonably would have expected success because of the *in vitro* immunization and challenge in mice experiments described by Brake.

Response to Arguments

Applicant's arguments about the prior art, Bowland et al., not teaching a vaccine comprising BVDV types 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

April 8, 2008

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648